K080738

Video Dental RF America

110 East Granada Boulevard, Suite 207
Ormond Beach, FL 32176
800-323-2690

www.videodental.com

PREMARKET SUMMARY
(As Required By 21 CFR 807393)

MAY 13 2008

Contact person: Claude Berthoin
Video Dental Concepts, Inc.
110 East Granada Boulevard
Suite 207
Ormond Beach, FL 32176
Phone: 800-323-2690

Alternate contact: Sue Williams

General Information

Proprietary or Trade Name: Dentron Sensor
Common/Usual Name: Dental Image Management System
Classification & Regulation Number: Class II, CCD area image sensor; MUH, MQB; 892.1650
Reason for Premarket Notification: Product manufactured in Louisiana and is new to the market.

The **intended device** is similar in intended use, material, safety and effectiveness in similar applications to: **CEFLA s.l.r.'s MyRay K061114, Air Technique's Accent K050693, and Julie Alliance's QuickRay DSX 730 K990002**.

The device is to be distributed by Dentron Systems, LLC in the United States.

The following voluntary standards are utilized in whole or in part:
UL 60601-1:2003, Medical Electrical Equipment, Part 1: General Requirements for Safety and Canadian deviations – see IMQ S.p.A. Test report n° 27SE00094 and CSA/UL certificate 231961;

EN 60601-1-2: 2001 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Test, See IMQ S.p.A Test report n° 80SF00347/1 and 80SF000347/2; and

IEC 60601-1-4: 2000 Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems, See IMQ S.p.A Test report n° 27SE00094.

The materials in the device are identical to materials used in the identified predicate device.

Comparison of the Dentron Sensor to the legally marketed predicate devices:

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Comparison Table	Dentron Senso	MyRay WDS	Accent	QuickRay
K#	TBD	K061114	K050693	K990002
Intraoral Sensor	CCD + fiber optic plate + scintillator	CCD + fiber optic plate + scintillator	CCD + scintillator	CCD + scintillator
Sensor size (active area)	Size 1: 30x20mm Size 2: 34x24mm	Size 1: 20x30mm Size 2: 24x34mm	Size 1: 20x30mm Size 2: 27.5x36.08mm	21.4x34mm
Sensor cable connection	Sealed at the factory	sealed at the factory	Sealed at the factory	Sealed at the factory
Theorical resolution	10 lp/mm	25 lp/mm	22.7 p/mm	23.8 lp/mm
Digitalization / Conversion Resolution	12 bits (4095 ADU)	12 bit, 4096 grey levels	12 bit, 4096 grey levels	12 bit, 4096 grey levels
Connection	Wired, USB to CCU	Wireless, Bluetooth	Wireless, Bluetooth	Wired, USB to CCU
Connection medium	CCU with USB cable	USB-Bluetooth adapter	USB-Bluetooth adapter	CCU with USB cable
Image file format	Greyscale	Greyscale, TWAIN compatible	Greyscale, TWAIN compatible	Greyscale, Proprietary
Power supply	Powered through USB connection	3xAA rechargeable batteries	4xAA rechargeable batteries	Power applied to CCU only via 12V power adapter
Sterile product	No	No	No	No
File capturing, management and storage	Existing Commercial software (not part of the device). DentalEye 510k #K012439	Commercial software (not part of the device)	Commercial software (not part of the device)	Commercial software (not part of the device)
PC minimum environment	Windows 2000 / XP	P III 800MHz, Windows XP, 256k RAM, 150M HDU, USB2port, 1024x768x16million color display	Intel P IV 2.8 GHz, Windows XP pro, 1G RAM, 120G HDU, USB 1.1 port, 1024x768x16million color display	P III 600MHz, Windows 98SE, XP 128K RAM, 10G HDU, 2 x USB ports (unspecified), 1024x768x16million color display

- concise summary for any performance testing in the submission

- The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. All the systems include a scintillator coupled to a digital image sensor, electronic circuits to analyze the digital image and transmit the digital image to a personal computer for viewing and further management of the file. The porposed and predicated devices are substantially equivalent, similar devices that have been used by dentists int he US since 1989 and well accepted.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Dentron Systems, LLC
% Mr. Claude D. Berthoin
President / Owner
Video Dental Concepts, Inc.
11 East Granada Boulevard, Suite 207
ORMOND BEACH FL 32176

Re: K080738
Trade/Device Name: Dentron Sensor
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB and MUH
Dated: March 13, 2008
Received: March 18, 2008

Dear Mr. Berthoin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Video Dental Concepts, Inc..

510(k) Number (if known): K080738

Device Name: Dentron Sensor

Indication For Use: The CCD area image sensor is intended to capture an intraoral x-ray image, when exposed to x-rays, for dental diagnostic purposes.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE).

Division Sign-Off
Office of Device Evaluation

510(k)_____

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080738